07-12-01

EMARY'S U.S. Patent Application of:

Filed:

For:

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Docket No. 01723

CERTIFICATE OF MAILING BY

Date of Deposit: July 11, 2001

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Jeffrey Owen Phillips Serial No.: 09/481,207

Benzimidazole Dosage Forms

and Method of Using Same

January 11, 2000

Novel Substituted

Examiner: Fan, J.

Group Art Unit: 1625

37 CFR 1.10 on the date indicated above and is addressed to U.S. Patent and Trademark Office, Washington, DC 20231

EL692808565US

Tim Hubalik (typed or printed name of person mailing paper

(signature of person mailing paper or fee)

TRANSMITTAL LETTER

Assistant Commissioner for Patents Washington, DC 20231

Dear Sir:

Enclosed herewith is the Information Disclosure Statement for the above-captioned case.

Also enclosed are:

- 1. Information Disclosure Statement;
- 2. PTO Form 1449;
- 3. One (1) copy of 333 references (Nos. 1-333, except Nos. 64-65, 88, 99, 108-110, 114, 118, 120, 132, 136, 139-188, 191, 193-196, 200-201 and 205-207). Please note that the missing copies will be supplied in the next several weeks, and that all of the references are being hand-delivered to the Examiner per her request;
- 4. Check in the amount of \$180; and
- 5. Return-receipt postcard.

The Commissioner is hereby authorized to charge any additional filing fees required under Rule 1.17 concerning this transaction, or to credit any overpayment to Deposit Account 13-0019. A duplicate copy of this Transmittal Letter is enclosed.

Respectfully submitted,

THE CURATORS OF THE UNIVERSITY OF MISSOURI

By: MAYER, BROWN & PLATT

By:

Joseph A. Mahoney (Reg. No. 38,956)

Dated: July 11, 2001

MAYER, BROWN & PLATT P.O. Box 2828 Chicago, IL 60609-2828 (312) 701-8979

Docket No. 01



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

atent Application of:)	
Jeffrey Owen Phillips)	
)	
09/481,207)	Examiner: Fan, J.
)	
January 11, 2000)	Group Art Unit: 1625
)	
Novel Substituted Benzimidazole)	
Dosage Forms and Method of)	
Using Same)	
	09/481,207 January 11, 2000 Novel Substituted Benzimidazole Dosage Forms and Method of	Jeffrey Owen Phillips) 09/481,207) January 11, 2000) Novel Substituted Benzimidazole Dosage Forms and Method of)

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents Washington, DC 20231

Dear Sir:

The following information is submitted pursuant to 37 CFR §§ 1.97-1.98 in accordance with Applicant's duty of disclosure under 37 CFR § 1.56(a). This submission is not intended to constitute an admission that any patent, publication or other information cited herein is "prior art" as to the invention claimed. In accordance with 37 CFR §§ 1.97(g)-(h), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that other material information as defined by 37 CFR § 1.56(a) exists.

Applicant submits herewith Form PTO 1449 listing the references cited in this Information Disclosure Statement. Applicant respectfully requests that the Examiner (1) initial each reference listed on the enclosed Form PTO 1449 indicating that the Examiner has considered and made those references of record in this application and (2) return a copy of the initialed Form PTO 1449 to Applicant.

07/16/2001 YPOLITE1 00000066 09481207 01 FC:126 180.00 OP Please note that this is Applicant's second Information Disclosure Statement submitted in this case. Applicant understands from the Examiner that Applicant's previous filing of February 28, 2001, which included 120 references, has never been delivered to the Examiner and is assumed to be lost by the PTO since Applicant does have confirmation of its receipt by the PTO. In addition, the Examiner has explained that the Information Disclosure Statement submitted with the parent application Ser. No. 08/680,376, now U.S. Pat. No. 5,840,737, cannot be located by the PTO. Consequently, the Examiner has asked that Applicant resubmit all such references, along with any new references.

Further, due to the large number of references submitted, the Examiner has requested that Applicant identify the most pertinent ones and highlight the relevant sections of the same.

Applicant has attempted to comply with this request. However, Applicant's action to comply is not to be construed as an admission that such identified references are prior art, or that they are more or less pertinent than any of the other references because reasonable minds could differ as to what is pertinent.

Please also note that Applicant is in the process of obtaining several of the references and will be submitting these along with the corresponding numbered tabs to be placed into the tabbed notebooks submitted to the Examiner herewith. All references are being hand-delivered to the Examiner pursuant to her request.

This Information Disclosure Statement is being filed after the first office action on the merits. Accordingly, Applicant encloses the fee of \$180.00 required under 37 CFR § 1.17(p). Should there be any additional fees required, the Commissioner is authorized to charge Deposit Account No. 13-0019.

Respectfully submitted,

THE CURATORS OF THE UNIVERSITY OF MISSOURI

By: MAYER, BROWN & PLATT

Bv:

Joseph A. Mahoney (Reg. No. 38,956)

Dated: July 11, 2001

MAYER, BROWN & PLATT P.O. Box 2828 Chicago, IL 60609-2828 (312) 701-8979

DATE: July 11, 2001 SHEET 1 of 14_

Form PTO - 1449 (Modified)

FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE (Modified) PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. SERIAL NO. 40015630-0004 09/481,207			
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	APPLICANT J. Phillips			
(Use several sheets if necessary) (37 CFR 1.98 (b))	FILING DATE January 11, 2000	GROUP 1625		

U.S. PATENT DOCUMENTS

EXAMINER									ISSUE			SUB	FILING
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1.		4	0	4	5	5	ဖ	4	08/30/77	Berntsson, et al.			
2.		4	1	8	2	7	6	6	01/08/80	Krasso, et al.			
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8.		4	6	3	6	4	9	9	01/13/87	Brandstrom, et al.		*	
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20.		5	0	9	3	1	3	2	03/03/92	Makino, et al.			
21.		5	0	9	3	3	4	2	03/03/92	Tomoi, et al.			
22.		5	1	0	6	8	6	2	04/21/92	Briving,et al.			
23.	·	5	2	1	5	9	7	4	06/01/93	Alminger, et al.			
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EXAMINER										DATE CONSIDERED			

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE (Modified) PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. SERIAL NO. 09/481,207					
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	APPLICANT J. Phillips					
(Use several sheets if necessary) (37 CFR 1.98 (b))	FILING DATE January 11, 2000	GROUP 1625				

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42.	П	5	7	1	4	5	0	4		Lindberg, et al.		
43.		5	7	1	4	5	0	5	02/03/98			
44.		5	7	3	1	0	0	2	03/24/98	Olovson, et al.		
45.		5	7	5	3	2	6	5	05/19/98	Bergstrand, et al.		
46.		5	7	6	6	6	2	2	06/16/98	Nelson		
47.		5	7	7	6	7	6	5	07/07/98	Graham, et al.		
48.		5	8	1	4	3	3	8	09/29/98	Veronesi	•	
49.		5	8	1	7	3	3	8	10/06/98	Bergstrand, et al.		
50.		5	8	4	0	7	3	7	11/24/98	Phillips		
51.		5	8	7	7	1	9	2	03/02/99	Lindberg, et al.		
52.		5	8	8	3	1	0	2	03/16/99	Hamley, et al.		
.53.		5	8	8	5_	_5	9	_4	.03/23/99	Nilsen, et al.		
54.		5	9	0	0	4	2	4	05/04/99	Kallstrom, et al.		
55.		5	9	2	9	2	4	4	07/27/99	Von Unge		
56.		5	9	3	9	0	9	1	08/17/99	Eoga, et al.	-	
57.		5	9	4	8	7	8	9	09/07/99	Larsson, et al.		
58.		5	9	5	5	1	0	7	09/21/99	Augello, et al.		
59.		5	9	5	8	9	5	5	09/28/99			
60.		5	9	6	2	0	2	2	10/05/99	Bolt, et al.		
61.		_	9	6	5	1	6	2	10/12/99	Fuisz, et al.		
62.			9	7	9	5	1	5	11/09/99	Olsson		
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6 0 1 3 2 8 1 01/11/00 Lundberg, et al. FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION

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64.		8	8	3	5	1			04/30/86	RO				
65.		2	1	8	9	6	9	8	11/04/87	UK				
66.		1	2	3	4	1	1	8	03/15/88	CA				
67.	0	5	1	9	4	2	2	5	08/03/93	JP/English Trans. Attached				
68.		9	4	0	0	1	1	2	01/06/94	WO				
69.		9	4	0	2	1	4	0	02/03/94	WO A1				
70.		9	5	3	2	9	5	7	12/07/95	WO A1				
71.		9	6	0	1	6	1	2	01/25/96	WO A1				
72.		9	6	0	1	6	2	2	01/25/96	WO A1				
73.		9	6	2	4	3	7	5	08/15/96	WO A1				
74.		9	7	2	5	0	3	0	07/17/97	WO A1				
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76.		9	7	4	8	3	8	0	12/24/97	WO A1				
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79.		9	8	5	0	0	1	9	11/12/98	WO A1				
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FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION

80.		9	8	5	3	8	0	3	12/03/98	WO A1
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82.		9	9	0	0	3	8	0	01/07/99	WO A1
83.		9	9	0	8	5	0	0	02/25/99	WO A2
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85.		9	9	2	7	9	1	7	06/10/99	WO A1
86.		9	9	2	9	3	2	0	06/17/99	WO A1
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91.		0	0	2	6	1	8	5	05/11/00	WO A2 & A3

OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

92	2.	"Agents for Control of Gastric Acidity and Treatment of Peptic Ulcers", Chapter 37, pp. 907-909, 1768.						
93	3.	"Omeprazole, An Updated Review of its Pharmacology and Therapeutic Use in Acid-Related Disorders" by D. McTavish, et al., <u>Drugs</u> , Vol. 42, No. 1, pp. 138-170 (1991).						
94	4.	"Omeprazole, Overview and Opinion" by S. Holt, et al., <u>Digestive Diseases and Sciences</u> , Vol. 36, No. 4, pp. 385-393 (April 1991).						
95	5.	"Pantoprazole, A Review of its Pharmacological Properties and Therapeutic Use in Acid-Related Disorders" by A. Fitton, et al., <u>Drugs</u> , Vol. 51, No. 3, pp. 460-482 (March 1996).						
96	6.	"Differential Stereoselective Pharmacolkinetics of Pantoprazole, a Proton Pump Inhibitor in Extensive and Poor Metabolizers of Pantoprazole – A Preliminary Study" by M. Tanaka, et al., Chirality, Vol. 9, pp. 17-21 (1997).						
97	7.	"A Prospective Study of Simplified Omeprazole Suspension for the Prophylaxis of Stress-related Mucosal Damage" by J. Phillips, et al., <u>Critical Care Medicine</u> , Vol. 24, No. 11, pp. 1793-1800 (1996).						
98	8.	"A Prospective Study of Omeprazole Suspension to Prevent Clinically Significant Gastrointestinal Bleeding From Stress Ulcers in Mechanically Ventilated Trauma Patients" by M. Lasky, et al., The Journal of Trauma: Injury Infection, and Critical Care, Vol. 44, No. 3, pp. 527-533 (March 1998).						
99	9.	"Effect of Combined Administration of Lansoprazole and Sofalcone on Microvascular and Connective Tissue Regeration After Ethanol-induced Mucosal Damage" by M. Nakamura, et al., Journal of Clinical Gastroenterology, Vol. 27, Supp. 1, pp. 170-77 (1998).						
10	00.	"The Effect of Omeprazole/Sodium Bicarbonate Solution Administration on the Accuracy of Subsequent pH Measurements Through the Nasogastric Tube" by J. Whipple, et al., <u>Critical Care Medicine</u> , Vol. 23, No. 1 Supplement, p. A69 [Date stamped in Howard University Library on January 13, 1995].						
EXAMINER		DATE CONSIDERED						
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DATE: July 11, 2001 SHEET _4_ of _14_

Form PTO - 1449 (Modified)

FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE	ATTY. DOCKET NO.	SERIAL NO.		
(Modified) PATENT AND TRADEMARK OFFICE	40015630-0004	09/481,207		
INFORMATION DISCLOSURE	APPLICANT			
STATEMENT BY APPLICANT	J. Phillips			
(Use several sheets if necessary)	FILING DATE	GROUP		
(37 CFR 1.98 (b))	January 11, 2000 1625			

OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

102 103 104 105		Subsequent pH Measurements Through the Nasogastric Tube" by J. Whipple, et al., Critical Care Medicine, Vol. 23, No. 1 Supplement, p. A69 (January 1995). [Date stamped in Walter Reed Army Medical Center Medical Library on January 17, 1995]. "The Effect of Omeprazole/Sodium Bicarbonate Solution Administration on the Accuracy of Subsequent pH Measurements Through the Nasogastric Tube" by J. Whipple, et al., Critical Care Medicine, Vol. 23, No. 1 Supplement, p. A69 (January 1995). [Date stamped in FDA Medical Library January 6, 1995]. "The Effect of Omeprazole/Sodium Bicarbonate Solution Administration on the Accuracy of Subsequent pH Measurements Through the Nasogastric Tube" by J. Whipple, et al., Critical Care Medicine, Vol. 23, No. 1 Supplement, p. A69 (January 1995). [Date stamped in University of Illinois on January 10, 1995]. "The Effect of Omeprazole/Sodium Bicarbonate Solution Administration on the Accuracy of Subsequent pH Measurements Through the Nasogastric Tube" by J. Whipple, et al., Critical Care Medicine, Vol. 23, No. 1 Supplement, p. A69 (January 1995). [Date stamped in Central DuPage Hospital Medical Library on January 10, 1995]. "The Effect of Omeprazole/Sodium Bicarbonate Solution Administration on the Accuracy of Subsequent pH Measurements Through the Nasogastric Tube" by J. Whipple, et al., Critical Care Medicine, Vol. 23, No. 1 Supplement, p. A69 (January 1995). [Date stamped in University Care Medicine, Vol. 23, No. 1 Supplement, p. A69 (January 1995). [Date stamped in University Care Medicine, Vol. 23, No. 1 Supplement, p. A69 (January 1995). [Date stamped in University Care Medicine, Vol. 23, No. 1 Supplement, p. A69 (January 1995). [Date stamped in University Care Medicine, Vol. 23, No. 1 Supplement, p. A69 (January 1995). [Date stamped in University Care Medicine, Vol. 23, No. 1 Supplement, p. A69 (January 1995). [Date stamped in University Care Medicine, Vol. 23, No. 1 Supplement, p. A69 (January 1995). [Date stamped in University Care Medicine, Vol. 23, No. 1 Supplement, p. A69 (J
103		Reed Army Medical Center Medical Library on January 17, 1995]. "The Effect of Omeprazole/Sodium Bicarbonate Solution Administration on the Accuracy of Subsequent pH Measurements Through the Nasogastric Tube" by J. Whipple, et al., Critical Care Medicine, Vol. 23, No. 1 Supplement, p. A69 (January 1995). [Date stamped in FDA Medical Library January 6, 1995]. "The Effect of Omeprazole/Sodium Bicarbonate Solution Administration on the Accuracy of Subsequent pH Measurements Through the Nasogastric Tube" by J. Whipple, et al., Critical Care Medicine, Vol. 23, No. 1 Supplement, p. A69 (January 1995). [Date stamped in University of Illinois on January 10, 1995]. "The Effect of Omeprazole/Sodium Bicarbonate Solution Administration on the Accuracy of Subsequent pH Measurements Through the Nasogastric Tube" by J. Whipple, et al., Critical Care Medicine, Vol. 23, No. 1 Supplement, p. A69 (January 1995). [Date stamped in Central DuPage Hospital Medical Library on January 10, 1995]. "The Effect of Omeprazole/Sodium Bicarbonate Solution Administration on the Accuracy of Subsequent pH Measurements Through the Nasogastric Tube" by J. Whipple, et al., Critical
103		"The Effect of Omeprazole/Sodium Bicarbonate Solution Administration on the Accuracy of Subsequent pH Measurements Through the Nasogastric Tube" by J. Whipple, et al., Critical Care Medicine, Vol. 23, No. 1 Supplement, p. A69 (January 1995). [Date stamped in FDA Medical Library January 6, 1995]. "The Effect of Omeprazole/Sodium Bicarbonate Solution Administration on the Accuracy of Subsequent pH Measurements Through the Nasogastric Tube" by J. Whipple, et al., Critical Care Medicine, Vol. 23, No. 1 Supplement, p. A69 (January 1995). [Date stamped in University of Illinois on January 10, 1995]. "The Effect of Omeprazole/Sodium Bicarbonate Solution Administration on the Accuracy of Subsequent pH Measurements Through the Nasogastric Tube" by J. Whipple, et al., Critical Care Medicine, Vol. 23, No. 1 Supplement, p. A69 (January 1995). [Date stamped in Central DuPage Hospital Medical Library on January 10, 1995]. "The Effect of Omeprazole/Sodium Bicarbonate Solution Administration on the Accuracy of Subsequent pH Measurements Through the Nasogastric Tube" by J. Whipple, et al., Critical
103		Subsequent pH Measurements Through the Nasogastric Tube" by J. Whipple, et al., Critical Care Medicine, Vol. 23, No. 1 Supplement, p. A69 (January 1995). [Date stamped in FDA Medical Library January 6, 1995]. "The Effect of Omeprazole/Sodium Bicarbonate Solution Administration on the Accuracy of Subsequent pH Measurements Through the Nasogastric Tube" by J. Whipple, et al., Critical Care Medicine, Vol. 23, No. 1 Supplement, p. A69 (January 1995). [Date stamped in University of Illinois on January 10, 1995]. "The Effect of Omeprazole/Sodium Bicarbonate Solution Administration on the Accuracy of Subsequent pH Measurements Through the Nasogastric Tube" by J. Whipple, et al., Critical Care Medicine, Vol. 23, No. 1 Supplement, p. A69 (January 1995). [Date stamped in Central DuPage Hospital Medical Library on January 10, 1995]. "The Effect of Omeprazole/Sodium Bicarbonate Solution Administration on the Accuracy of Subsequent pH Measurements Through the Nasogastric Tube" by J. Whipple, et al., Critical
104		Care Medicine, Vol. 23, No. 1 Supplement, p. A69 (January 1995). [Date stamped in FDA Medical Library January 6, 1995]. "The Effect of Omeprazole/Sodium Bicarbonate Solution Administration on the Accuracy of Subsequent pH Measurements Through the Nasogastric Tube" by J. Whipple, et al., Critical Care Medicine, Vol. 23, No. 1 Supplement, p. A69 (January 1995). [Date stamped in University of Illinois on January 10, 1995]. "The Effect of Omeprazole/Sodium Bicarbonate Solution Administration on the Accuracy of Subsequent pH Measurements Through the Nasogastric Tube" by J. Whipple, et al., Critical Care Medicine, Vol. 23, No. 1 Supplement, p. A69 (January 1995). [Date stamped in Central DuPage Hospital Medical Library on January 10, 1995]. "The Effect of Omeprazole/Sodium Bicarbonate Solution Administration on the Accuracy of Subsequent pH Measurements Through the Nasogastric Tube" by J. Whipple, et al., Critical
104		Medical Library January 6, 1995]. "The Effect of Omeprazole/Sodium Bicarbonate Solution Administration on the Accuracy of Subsequent pH Measurements Through the Nasogastric Tube" by J. Whipple, et al., Critical Care Medicine, Vol. 23, No. 1 Supplement, p. A69 (January 1995). [Date stamped in University of Illinois on January 10, 1995]. "The Effect of Omeprazole/Sodium Bicarbonate Solution Administration on the Accuracy of Subsequent pH Measurements Through the Nasogastric Tube" by J. Whipple, et al., Critical Care Medicine, Vol. 23, No. 1 Supplement, p. A69 (January 1995). [Date stamped in Central DuPage Hospital Medical Library on January 10, 1995]. "The Effect of Omeprazole/Sodium Bicarbonate Solution Administration on the Accuracy of Subsequent pH Measurements Through the Nasogastric Tube" by J. Whipple, et al., Critical
104		"The Effect of Omeprazole/Sodium Bicarbonate Solution Administration on the Accuracy of Subsequent pH Measurements Through the Nasogastric Tube" by J. Whipple, et al., Critical Care Medicine , Vol. 23, No. 1 Supplement, p. A69 (January 1995). [Date stamped in University of Illinois on January 10, 1995]. "The Effect of Omeprazole/Sodium Bicarbonate Solution Administration on the Accuracy of Subsequent pH Measurements Through the Nasogastric Tube" by J. Whipple, et al., Critical Care Medicine , Vol. 23, No. 1 Supplement, p. A69 (January 1995). [Date stamped in Central DuPage Hospital Medical Library on January 10, 1995]. "The Effect of Omeprazole/Sodium Bicarbonate Solution Administration on the Accuracy of Subsequent pH Measurements Through the Nasogastric Tube" by J. Whipple, et al., Critical
104		Subsequent pH Measurements Through the Nasogastric Tube" by J. Whipple, et al., Critical Care Medicine, Vol. 23, No. 1 Supplement, p. A69 (January 1995). [Date stamped in University of Illinois on January 10, 1995]. "The Effect of Omeprazole/Sodium Bicarbonate Solution Administration on the Accuracy of Subsequent pH Measurements Through the Nasogastric Tube" by J. Whipple, et al., Critical Care Medicine, Vol. 23, No. 1 Supplement, p. A69 (January 1995). [Date stamped in Central DuPage Hospital Medical Library on January 10, 1995]. "The Effect of Omeprazole/Sodium Bicarbonate Solution Administration on the Accuracy of Subsequent pH Measurements Through the Nasogastric Tube" by J. Whipple, et al., Critical
105	•	Care Medicine, Vol. 23, No. 1 Supplement, p. A69 (January 1995). [Date stamped in University of Illinois on January 10, 1995]. "The Effect of Omeprazole/Sodium Bicarbonate Solution Administration on the Accuracy of Subsequent pH Measurements Through the Nasogastric Tube" by J. Whipple, et al., Critical Care Medicine, Vol. 23, No. 1 Supplement, p. A69 (January 1995). [Date stamped in Central DuPage Hospital Medical Library on January 10, 1995]. "The Effect of Omeprazole/Sodium Bicarbonate Solution Administration on the Accuracy of Subsequent pH Measurements Through the Nasogastric Tube" by J. Whipple, et al., Critical
105	•	of Illinois on January 10, 1995]. "The Effect of Omeprazole/Sodium Bicarbonate Solution Administration on the Accuracy of Subsequent pH Measurements Through the Nasogastric Tube" by J. Whipple, et al., Critical Care Medicine, Vol. 23, No. 1 Supplement, p. A69 (January 1995). [Date stamped in Central DuPage Hospital Medical Library on January 10, 1995]. "The Effect of Omeprazole/Sodium Bicarbonate Solution Administration on the Accuracy of Subsequent pH Measurements Through the Nasogastric Tube" by J. Whipple, et al., Critical
105	•	"The Effect of Omeprazole/Sodium Bicarbonate Solution Administration on the Accuracy of Subsequent pH Measurements Through the Nasogastric Tube" by J. Whipple, et al., Critical Care Medicine, Vol. 23, No. 1 Supplement, p. A69 (January 1995). [Date stamped in Central DuPage Hospital Medical Library on January 10, 1995]. "The Effect of Omeprazole/Sodium Bicarbonate Solution Administration on the Accuracy of Subsequent pH Measurements Through the Nasogastric Tube" by J. Whipple, et al., Critical
105	•	Subsequent pH Measurements Through the Nasogastric Tube" by J. Whipple, et al., <u>Critical Care Medicine</u> , Vol. 23, No. 1 Supplement, p. A69 (January 1995). [Date stamped in Central DuPage Hospital Medical Library on January 10, 1995]. "The Effect of Omeprazole/Sodium Bicarbonate Solution Administration on the Accuracy of Subsequent pH Measurements Through the Nasogastric Tube" by J. Whipple, et al., <u>Critical</u>
		Care Medicine, Vol. 23, No. 1 Supplement, p. A69 (January 1995). [Date stamped in Central DuPage Hospital Medical Library on January 10, 1995]. "The Effect of Omeprazole/Sodium Bicarbonate Solution Administration on the Accuracy of Subsequent pH Measurements Through the Nasogastric Tube" by J. Whipple, et al., Critical
		DuPage Hospital Medical Library on January 10, 1995]. "The Effect of Omeprazole/Sodium Bicarbonate Solution Administration on the Accuracy of Subsequent pH Measurements Through the Nasogastric Tube" by J. Whipple, et al., Critical
		"The Effect of Omeprazole/Sodium Bicarbonate Solution Administration on the Accuracy of Subsequent pH Measurements Through the Nasogastric Tube" by J. Whipple, et al., Critical
		Subsequent pH Measurements Through the Nasogastric Tube" by J. Whipple, et al., Critical
106		
106		Care Medicine, Vol. 23, No. 1 Supplement p. A69 (January 1995) [Date stamped in University
106	+	
106		of Missouri Health Sciences Library January 6, 1995].
		"The Effect of Omeprazole/Sodium Bicarbonate Solution Administration on the Accuracy of
		Subsequent pH Measurements Through the Nasogastric Tube" by J. Whipple, et al., Critical
		Care Medicine, Vol. 23, No. 1 Supplement, p. A69 (January 1995). [Although allegedly date
	i	stamped in St. Vincent's Hospital Medical Library on January 3, 1995, interviews of library
	1	personnel revealed that this Supplement was not received until Jan. 9, 1995, as the January 9,
		1995 date is found in their computerized database.]
107	.	"Lansoprazole Capsules and Amoxicillin Oral Suspension in the Treatment of Peptic Ulcer
		Disease" by J. Hatlebakk, et al., Scand. J. Gastroenterol., Vol. 30, No. 11, pp. 1053-57 (1995).
108	. -	"Nicotinamide Pharmacokinetics in Humans: Effect of Gastric Acid Inhibition, Comparison of
		Rectal vs Oral Administration and the Use of Saliva for Drug Monitoring" by M.R. Stratford, et al.
		<u>J Cancer, Vol. 74, No. 1, pp. 16-21 (July 1996).</u>
109		"Comments of the Report of 'Association' of Omeprazole with DNA by Phillips, et al." by S.P.
		Adams Mutagenesis, Vol. 7, No. 5, pp. 395-396 (September 1992).
110		"Interaction of Omperazole with DNA in Rat Issues" by D.H. Phillips, Mutagenesis, Vol. 7, No. 4,
		pp. 277-283 (July 1992).
111.		"Stability of Omeprazole in an Extemporaneously Prepared Oral Liquid" by R.A. Quercia, et al.,
İ		American Journal of Health-System Pharmacy, Vol. 54, pp. 1833-1836 (August 15, 1997).
112	.	"Simplified Omeprazole Solution For The Prophylaxis of Stress-Related Mucosal Damage In
		Critically III Patients", by J. Phillips, et al., Critical Care Medicine, Vol. 22, No. 1, p. A53 (January
		1994).
113		"Effective Gastric Acid Suppression After Oral Administration of Enteric-Coated Omeprazole
		Granules" by M.A. Mohiuddin, et al., Digestive Diseases and Sciences, Vol. 42, No. 4, pp. 715-
		719 (April 1997).
114.		"Endoscopic Topical Therapy for the Treatment of Heliobacter Pylori Infection" by K. Kihira, et
		al. <u>J Gastroenterol</u> , Vol. 31, Suppl 9, pp. 66-68 (November 1996).
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FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE	ATTY. DOCKET NO.	SERIAL NO.
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OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

	115.	"Pharmacokinetic Evaluation of Omeprazole Suspension Following Oral Administration in Rats: Effect of Neutralization of Gastric Acid" by K. Watanabe, et al., <u>Acta Med Okayama</u> , Vol. 50, No. 4, pp. 219-222 (August 1996).	
	116.	"Pharmacokinetics of Lansoprazole in Hemodialysis Patients" by M. Karol, et al., <u>J Clin</u> <u>Pharmacol</u> , Vol. 35, pp. 815-820 (August 1995).	
	117.	"Omeprazole: Pharmacokinetics and Metabolism in Man" by C. Cederberg, et al., <u>Scand. J. Gastroenterol.</u> , Vol. 24, Suppl. 166, pp. 33-40 (1989).	
	118.	"Synthesis and Structure-Activity Relationships of Substituted 2-[2-imidazolylsulfinyl)methyl] Anilines As A New Class of Gastric H+/K(+)-ATPase Inhibitors. II." by T. Yamakawa, Chem Pharm Bull (Tokyo), Vol. 40, No. 3, pp. 675-682 (March 1992).	
	119.	"Studies on (H(+)-K+)-ATPase Inhibitors of Gastric Acid Secretion. Prodrugs of 2-[(2-Pyridinylmethyl)sulfinyl]benzimidazole Proton-Pump Inhibitors" by J. Sih, et al., <u>Journal of Medicinal Chemistry</u> , Vol. 34, No. 3, pp. 1049-1062 (March 1991).	
	120.	"Effects of Pantoprazole, A Novel H+/K+-ATPase Inhibitor, On Duodenal Ulcerogenic and Healing Responses in Rats: A Comparative Study with Omeprazole and Lansoprazole" by Takeuchi, et al., J. Gastroenterol. Hepatol., Vol. 14, No. 3, p. 251-57 (1999).	
	121.	"Pharmacokinetics, Metabolism and Interactions of Acid Pump Inhibitors: Focus on Omeprazole, Lansoprazole and Pantoprazole" by T. Andersson, <u>Clin. Pharacokinet.</u> , Vol. 31, No. 1, pp. 9-28 (July 1996).	
	122.	"Nasogastric Administration of Omeprazole", <u>The Australian Journal of Hospital Pharmacy</u> , Vol. 28, No. 3, pp. 174-176 (1998).	
	123.	"Bioavailability and Efficacy of Omeprazole Given Orally and By Nasogastric Tube" by C. Larson, et al., <u>Digestive Diseases and Sciences</u> , Vol. 41, No. 3, pp. 475-479 (March 1996).	
	124.	"Nasogastic Omeprazole: Effects on Gastric pH in Critically III Patients" by D. Balaban, et al., The American Journal of Gastroenterolgy, Vol. 92, No. 1, pp. 79-83 (1997).	
_	125.	"Comparison of 24-hour Intragastric pH Using Four Liquid Formulations of Lansoprazole and Omeprazole" by V. Sharma, <u>American Journal of Health-System Pharmacists</u> , Vol. 56, Suppl 4, pp. S18-S21(December 1, 1999).	
	126.	"The Stability of Simplified Lansoprazole Suspension (SLS)" by J. Phillips, et al., Gastroenterology, Vol. 116, No. 4, pg. G0382 (April 1999).	
	127.	"Effect on 24-hour Intragastric Acidity of Simplified Omeprazole Solution (SOS) Administered Via Gastrostomy", by V. Sharma, et al., AJG, Vol. 92, No. 9, p. 1625, Section 169 (1997).	
	128.	"Simplified Lansoprazole Suspension (SLS): A Proton Pump Inhibitor (PPI) In A Liquid Formulation That Works" by V. Sharma, et al., AJG, p. 1647, Section 153 (September 1998).	
ŕ	129.	"Simplified Lansoprazole Suspension – A Liquid Formulation of Lansoprazole – Effectively Suppresses Intragastric Acidity When Administered Through a Gastrostomy" by V. Sharma, et al., The American Journal of Gastroenterology, Vol. 94, No. 7, pp. 1813-1817 (July 1999).	
	130.	"The Effects on Intragastric Acidity of Per-Gastrostomy Administration of An Alkaline Suspension of Omeprazole" by V. Sharma, et al., <u>Aliment Pharmocol Ther</u> , Vol. 13, pp. 1091-1095 (1999).	
EXAMINER		DATE CONSIDERED	

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

DATE: July 11, 2001 SHEET _6_ of _14_

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OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

131.	"A Multicenter, Prospective, Randomized Clinical Trial of Continuous Infusion I.V. Ranitidine vs. Omeprazole Suspension in the Prophylaxis of Stress Ulcers" by J. Phillips, et al., <u>Critical Care Medicine</u> , Vol. 26, No. 1 (Suppl.), p. A101, No. 222 (1998).		
132.	"Gastrointestinal Drugs", <u>The American Medical Association Drug Evaluation</u> , Vol. 2, The American Medical Association, Chicago, 1:8 (Bennett & Dickson, eds.).		
133.	"Pharmacokinetics of [14C]Omeprazole in Patients with Liver Cirrhosis" by T. Andersson, et al., Clin Pharmacokinet., Vol. 24, No. 1, pp. 71-78 (1993).		
134.	"Pharmacokinetics and Bioavailability of Omeprazole After Single and Repeated Oral Administration in Healthy Subjects" by T. Andersson, et al., <u>Br. J. Clin. Pharmac.</u> , Vol. 29, pp. 557-563 (1990).		
135.	"Development of An Oral Formulation of Omeprazole" by A. Pilbrant, et al., Scand. J. Gastrolenterol, Vol. 20, (Suppl. 108) pp. 113-120 (1985).		
136.	"Pharmacokinetics of Various Single Intravenous and Oral Doses of Omeprazole" by T. Andersson, et al., European Journal of Pharmacology, Vol. 39, pp. 195-197 (1990).		
137.	"Pharmacokinetic Study of Omeprazole in Elderly Healthy Volunteers" by S. Landahl, et al., Clin. Pharmacokinet., Vol. 23, No. 6, pp. 469-476 (1992).		
138.	"The Pharmacokinetics of Omeprazole in Humans - A Study of Single Intravenous and Oral Doses" by C. Regardh, et al., Therapeutic Drug Monitoring, Vol. 12, No. 2, pp. 163-172 (1990).		
139.	"Bolus or Intravenous Infusion of Rantidine: Effects on Gastric pH and Acid Secreation" by Ballesteros, et al., Ann. Intern. Med., Vol. 112, pp. 334, 339 (1990).		
140.	"Therapeutic Use of Omeprazole For Refractory Stress-Induced Gastric Mucosal Hemorrage" by Barie & Hariri, Critical Care Medicine, Vol. 20, pp. 899-901 (1992).		
141.	"Let's Agree on Terminology: Definition of Sepsis" by Bone, <u>Critictical Care Medicine</u> , Vol. 19, p. 27 (1991).		
142.	"Antacids vs. Sucralfate in Preventing Acute Gastrointestinal Tract Bleeding in Abdominal Aortic Surgery" by Borrero, et al., Arch. Surg., Vol. 121, pp. 810-12 (1986).		
143.	The Pharmacologic Basis of Therapeutics by Brunton, p. 907 (1990).		
144.	"Central Nervous System Reactions to Histamine-2 Receptor Blockers" by Cantu & Korek, Vol. 114, pp. 1027-34 (1994).		
145.	"Comparison of Acid Neutralizing and Non-acid Neutralizing Stress Ulcer Prophylaxis in Thermally Injured Patients" by Cioffi, et al., Vol. 36, pp. 541-47 (1994).		
146.	"Risk Factors For Gastrointestinal Bleeding in Critcially III Patients" by Cook, et al., Vol. 330, pp. 377-81 (1994).		
147.	"Stress Ulcer Prophylaxis in the Critically III: A Meta Analysis" by Cook, et al., Vol. 91, pp. 519-27 (1991).		
148.	"Nasocomial Pneumonia and the Role of Gastric pH: A Meta Analysis" by Cook, et al., Vol. 100, pp. 7-13 (1991).		
149.	"Acute Gastroduodenal Disease After Themal Injury: An Endoscopic Evaluation of Incidence and Natural History" by Czaja, et al., Vol. 291, pp. 925-29 (1974).		
150.	"Does pH Paper Accurately Reflect Gastric pH?" by Dobkin, et al., Vol. 18, pp. 985-88 (1990).		
EXAMINER	DATE CONSIDERED		
	ation considered. Draw line through citation if not in conformance and		
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OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

151.	"Nosocomial Pneumonia in Intubated Patients Given Sucralfate As Compared With Antacids or Histamine Type 2 Blockers" by Driks et al., N. Eng. J. Med., Vol. 317, pp. 1376-82 (1987).	
152.	"Prospective Trial Comparing a Combination pH Probe-Nasogastric Tube With Aspirated Gastric pH" by Eisenberg, et al., <u>Critical Care Medicine</u> , Vol. 18, 1092-95 (1990).	
153.	"Pneumonia and Stress Ulceration in Severely Injured Patients" by Fabian et al., Vol. 128, p. 1855 (1993).	
154.	"Substituted Benzimidazoles Inhibit Gastric Acid Secretions by Blocking H+/K+- ATPase" by Fellenius, et al., Nature, Vol. 290, pp. 159-61 (1981).	
155.	Predictive Value of Intramural pH and Other Risk Factors For Massive Bleeding From Stress Ulceration" by Fiddian-Green, et al., Gastroenterology, Vol. 8, pp. 613-20 (1983).	
156.	"Function and Structure of Parietal Cells After H+/K+-ATPase Blockade" by Fryklund, et al., Am. J. Physiol., Vol. 254, pp. G399-407 (1988).	
157.	"Thrombocytopenia Associated with Hypersensitivity to Rantidine: Possible Cross-Reactivity" by Gafter, et al., Vol. 64, pp. 560-62 (1989).	
158.	"CDC Definitions for Nosocomial Infections" by Garner, et al., Am. J. Infect. Control, Vol. 16, pp. 128-40 (1988).	
159.	"Intragastric pH Measurement Using a Novel Disposable Sensor" by Heath, et al., Intes. Care Med., Vol. 14, pp. 232-35 (1988).	
160.	"Effect of Intravenous Infusion of Omeprazole and Rantidine on Twenty-Four-Hour Intragastric pH" by Kiilerich, et al., Vol. 56, pp. 25-30 (1995).	
161.	"Prevention of Upper Gastrointestinal Bleeding in Long Term Ventilated Patients" by Laggner, et al., Am. J. Med., Vol. 86, Suppl. 6A, pp. 81-84 (1989).	
162.	"Gastric Response to Severe Head Injury" by Larson, et al., Am. J. Surg., Vol. 147, pp. 97-105 (1984).	
163.	"Pathogenesis, Diagnosis and Treatment of Acute Gastric Mucosa Lesions" by Marrone & Silen, Clin. Gastroenterol., Vol. 13, pp. 635-50 (1984).	
164.	"Continuous Intravenous Cimetidine Decreases Stress-Related Upper Gastrointestinal Hemorrhage" by Martin, et al., Critical Care Medicine, Vol. 21, pp. 19-39 (1993).	
165.	"Evaluation of Various Techniques to Monitor Intragastric pH" by Meiners et al., Arch. Surg., Vol. 117, pp. 288-91 (1982).	
166.	"Electrolyte and Acid-base Disorders" by Oh & Carroll, The Pharmacologic Approach to the Critically III Patient, pp. 966-67 (Chernow, B. ed. 1994).	
167.	"Control of Gastric pH With Cimetidine Boluses Versus Primed Infusions" by Ostro et al., Gastroenterology, Vol. 89, pp. 532-37 (1985).	
168.	"Cimetidine for Prevention and Treatement of Gastroduodenal Mucosal Lesions in Patients" by Peura & Johnson, Ann. Intern. Med., Vol. 103, pp. 173-177 (1985).	
169.	"Occurrence of Nasocomial Pneumonia in Mechanically Ventilated Trauma Patients" by Pickworth, et al., Critical Care Medicine, Vol. 12, pp. 1856-62 (1993).	
170.	"Methods of Prophylaxis in Stress Ulcer Disease" by Priebe & Skillman, World J. Surg., Vol. 5, pp. 223-33 (1981).	
EXAMINER	DATE CONSIDERED	
<u> </u>	ation considered. Draw line through citation if not in conformance and	

DATE: July 11, 2001 SHEET _8 of _14_

Form PTO - 1449 (Modified)

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OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

171.	"Nasocomial Pneumonia During Stress Ulcer Prophylaxis With Cimetidine and Sucralfate" by		
	Ryan, et al., <u>Arch. Surg.</u> , Vol. 128, pp. 1353-57 (1993).		
172.	"Clinically Important Adverse Effects and Drug Interactions With H2-receptor Antagonists: An Update" by Sax, Pharmacotherapy, Vol. 7, pp. 110S-115S (1987).		
173.	"Stress Ulcer Prophylaxis: Still a Valid Option in the 1990s?" by Schepp, Vol. 54, pp. 189-99 (1993).		
174.	"Prophylactic Therapy for Acute Ulcer Bleeding: A Reappraisal" by Schuman, et al., Ann. Intern. Med., Vol. 106, pp. 562-67 (1987).		
175.	"Stress Ulcer Prophylaxis: In Whom? With What?" by Schuster, Critical Care Medicine, Vol. 21, pp. 4-6 (1993).		
176.	"A Dosage Alternative for H-2 Receptor Antagonists, Continuous-Infusion" by Siepler, Clin. Ther., Vol. 8, pp. 24-33 (1986).		
177.	"Role of Gastric Colonizmation in the Development of Pneumonia in Critically III Trauma Patients" by Simms, et al., <u>J. Trauma</u> , Vol. 31, pp. 531-36 (1991).		
178.	"Respiratory Failure, Hypotension, Sepsis and Jaundice: A Clinical Syndrome Associated With Lethal" by Skillman, et al., Am. J. Surg., Vol. 117, pp. 523-30 (1969).		
179.	"The Gastric Mucosal Barrier: Clinical and Experimental Studies In Critically III and Normal Man" by Skillman, et al., Ann. Surg., Vol. 172, pp. 564-84 (1970).		
180.	"Changing Perspectives of Stress Gastritis Prophylaxis" by Smythe & Zarowitz, Ann. Pharmacother., Vol. 28, pp. 1073-84 (1994).		
181.	"Thrombocytopenia Associated With Rantidine" by Spychal & Wickman, <u>Br. Med. J.</u> , Vol. 291, p. 1687 (1985).		
182.	"Stress Ulcer Prophylaxis - Quo Vadis?" by Tryba, <u>Intens. Care Med.</u> , Vol. 20, pp. 311-13 (1994).		
183.	"Risk of Acute Stress Bleeding and Nosocomial Pneumonia in Ventilated Intensive Care Patients. Sucralfate vs. Antacids" by Tryba, Am. J. Med., Vol. 87 (3B) 117-24 (1987).		
184.	"Side Effects of Ranitidine" by Vial, et al., <u>Drug Saf.</u> , Vol. 6, pp. 94-117 (1991).		
185.	"The Relationship Between Gastric Acid Secretion and Gastric H+/K+-ATPase Activity" by Wallmark, et al., J. Biol. Chem., Vol. 260, pp. 13681-84 (1985).		
186.	"Tolerance During Dosing with H2 Receptor Antagonists: An Overview" by Wilder-Smith & Merki, Scand. J. Gastroenterol., Vol. 27, Suppl. 193, pp. 14-19 (1992).		
187.	"The Prevention of Gastro-Intestinal Tract Bleeding in Patients in an Intensive Care Unit" by Zinner, et al., Surg. Gynecol. Obstet., Vol. 153, pp. 214-20 (1981).		
188.	"Influence of Insulin Antibodies on Pharmacokinetics and Bioavailability of Recombinant Human" by Gray, et al., British Med. J., Vol. 290, pp. 1687-90 (1985).		
189.	"Nasogastric Administration of Omeprazole for Control of Gastric pH" by M. Carroll, et al., 10 th World Congresses of Gastroenterology, Abstracts (October 2-7, 1994).		
190.	"A Lansoprazole Suspension Formulation As An Alternative to Capsules for Oral Administration" by S. Lockhart, et al., World Congresses of Gastroenterology, Abstract Exh A2074 (September 6-11, 1998).		
EXAMINER	DATE CONSIDERED		
EXAMINER: Initial citat not considered. Include	ltion considered. Draw line through citation if not in conformance and de copy of this form with next communication to applicant.		

DATE: July 11, 2001 SHEET _9_ of _14_

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OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

	191.	"Gastric Acid Antisecretory Effect of Two Different Dosage Forms of Omeprazole During Prolonged Oral Treatment in the Qastric Fistula Dog" by Larsson, et al., Vol. 23, No. 8, pp. 1013-19 (1988).
1	192.	"Effect of Various Salts on the Stability of Lansoprazole, Omeprazole, and Pantoprazole as Determined by High-Performance Liquid Chromatography" by A. Ekpe, et al., <u>Drug</u> Development and Industrial Pharmacy, Vol. 25, No. 9, pp. 1057-1065 (1999).
	193.	"Inhibition of Gastric Secretion by Omeprazole and Efficacy of Calcuim Carbonate in the Control of Hyperphosphatemia in Patients on Maintenance Hemodialysis" by Sechet, et al., Nephrologie, Vol. 20, No. 4, pp. 213-16 (1999).
	194.	"Role of the Time of Administration of Calcium Carbonate in the Control of Hyperphophatemia in Patients on Maintenance Hemodialysis" by Sechet, et al., Nephrologie, Vol. 20, No. 4, pp. 209-12 (1999).
	195.	Onset of Action of Antisecretory Drugs: Beneficial Effects of a Rapid Increase in Intragastric pH in Acid Reflux Disease" by Pipkin, et al, <u>Scand. J. Gastroenterol. Supp.</u> , Vol. 230, pp. 3-8 (1999).
1	196.	"Omeprazole Disposition in Humans" by Regardh, et al., <u>Ther. Drug Monit.</u> , Vol. 12, No. 2, pp. 165 (1990).
	197.	"Evaluation of Buffering Capacity and Acid Neutralizing pH Time Profile of Antacids" by M. Lin, et al., J Formos Med Assoc, Vol. 97, No. 10, pp. 704-710 (1998).
1	198.	"A Study of Antacid Buffers: I. The Time Factor in Neutralization of Gastric Acidity", by J. Holbert, et al., <u>Journal of The American Pharmaceutical Association (Scientific Edition)</u> , Vol. 36, pp. 149-151 (1947).
1	199.	"Buffered and Isotonic Solutions", Physical Pharmacy, Chapter 8, pp. 169-189.
2	200.	"Influence of Insulin Antibodies on Pharmacokinetics and Bioavailability of Recombinant Human" by Gray, et al., British Medical Journal, 290: 1687-1690 (1985).
2	201.	"Inhibition of Basal and Betazole - and Sham-Feeding-Induced Acid Secretion by Omeprozole in Man" by Lind, et al., Scand. J. Gastroenterol, 21:1004-1010 (1986).
2	202.	"Lansoprazole: Phase I Study of Lansoprazole (AG-1749) Antiulcer Agent (Tablet Form)" by A. Nakagawa, et al., pp. 33-34 (1991).
2	203.	"Pantoprozole Bicarbonate Suspension (PBS) Provides Oral Bioavailability Comparable To Tablet" by J. Paul, et al., <u>Critical Care Medicine</u> , (Feb. 2001).
2	204.	Physical Pharmacy - Physical Chemicals Principles in the Pharmaceutical Sciences, Fourth Edition, by A. Martin, et al. (1993).
2	205.	"Journal of Clinical Therapeutics & Medicines" by Nakagawaa, et al., Vol. 7, No. 1, pp. 33-50 (1191).
2	206.	Organic Chemistry by Wade, Pritice-Hall, Inc., p. 349 (1987).
2	207.	"The Effect of Omeprazole/Sodium Bicarbonate Solution Administration on the Accuracy of Subsequent pH Measurements Through the Nasogastric Tube" by J. Whipple, et al., Vol. 28, No. 1 (Suppl), p. A69 (January 1995).
EXAMINER		DATE CONSIDERED
EXAMINER: In not considered	itial citat d. Includ	tion considered. Draw line through citation if not in conformance and de copy of this form with next communication to applicant.

DATE: July 11, 2001 SHEET _10_ of _14_



FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE	ATTY. DOCKET NO.	SERIAL NO.
(Modified) PATENT AND TRADEMARK OFFICE	40015630-0004	09/481,201
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	APPLICANT J. Phillips	
(Use several sheets if necessary) (37 CFR 1.98 (b))	FILING DATE January 11, 2000	GROUP 1625

OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

208.	"High Acid Buffering Capacity of Protein Hydrolysate Infant Formulas" by I. Korponay-Szabo, et al., <u>Journal of Pediatric Gastroenterology and Nutrition</u> , Vol. 31, Supplement 2, Abstract 956 (August 5-9, 2000).
209.	"Esomeprazole" by C. Spencer, et al., <u>Drugs 2000</u> , Vol. 60, No. 2, pp. 321-329 (August 2000).
210.	"Zollinger-Ellison Syndrome - Clinical Presentation in 261 Patients" by P. Roy, et al., Medicine, Vol. 79, No. 6, pp. 379-411 (2000).
211.	"Overuse of Proton Pump Inhibitors" by M. Naunton, et al., <u>Journal of Clinical Pharmacy and Therapeutics</u> , Vol. 25, pp. 333-340 (2000).
212.	"The Proton-Pump Inhibitors: Similarities and Differences" by J. Horn, Clinical Therapeutics, Vol. 22, No. 3, pp. 266-280 (2000).
213.	"Pantoprazole: A New Proton Pump Inhibitor" by P. Jungnickel, Clinical Therapeutics, Vol. 22, No. 11, pp. 1268-1293 (2000).
214.	"Rabeprazole for the Prevention of Pathologic and Symptomatic Relapse of Erosive or Ulcerative Gastroesophageal Reflux Disease" by A. Caos, et al., <u>The American Journal of Gastroenterology</u> , Vol. 95, No. 11, pp. 3081-3088 (2000).
215.	"The Stability of Simplified Omeprazole Suspension (SOS)" by J. Phillips, et al., <u>Critical Care Medicine</u> , Vol. 26, No. 1 (Suppl.), pg. A101, No. 221 (1998).
216.	"A Multicenter Prospective, Randomized Clinical Trial of Continuous Infusion I.V. Ranitidine vs. Omeprazole Suspension in The Prophylaxis of Stress Ulcers" by J. Phillips, et al., <u>Critical Care Medicine</u> , Vol. 26, No. 1 (Suppl.), pg. A101, No. 222 (1998).
217.	(Deleted)

EXAMINER	DATE CONSIDERED	
EXAMINER: Initial citation considered. Draw line not considered. Include copy of this form with n		

(Form PTO-1449)

DATE: July 11, 2001 SHEET _11_ of _14_





FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE (Modified) PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. 40015630-0004	SERIAL NO. 09/481,207
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	APPLICANT J. Phillips	
(Use several sheets if necessary) (37 CFR 1.98 (b))	FILING DATE January 11, 2000	GROUP 1625

U.S. PATENT DOCUMENTS

EXAMINER									ISSUE			SUB	FILING
INITIAL		PA1	ΓEΝ	ΤN	IUM	BEF	₹		DATE	PATENTEE	CLASS	CLASS	DATE
218.		4	2	5	5	4	3	1	03/10/81	Junggren, et al.			
219.		4	3	5	9	4	6	5	11/16/82	Ruwart			
220.		4	4	1	4	2	1	6	11/08/83	Kawakita, et al.			
221.		4	5	0	8	9	0	5	04/02/85	Junggren, et al.			
222.	•	4	9	6	5	3	5	1	10/23/90				
223.		4	9	8	5_	5	4	8	01/15/91	Caruso, et al.			
224.		5	3	3	9	7	0	0	08/23/94	Wright, et al.			
225.		5	4	4	7	9	1	8	09/05/95	McCullough			
226.		5	5	0	4	0	8	2	04/02/96	Kawakita, et al.			
227.		5	6	3	9	4	7	8	06/17/97	Makino, et al.			
228.		5	7	6	6	6	2	2	06/16/98	Nelson			
229.		6	0	1	7	5	6	0	01/25/00	Makino, et al.			
230.		6	0	တ	0	8	2	7	07/18/00				
231.		6	1	2	3	9	6	2	09/26/00	Makino, et al.			
232.		6	1	2	4	4	6	4	09/26/00				
233.		6	1	3	2	7	7	0	10/17/00				
234.		6	1	3	2	7	7	1	10/17/00				
235.		6	1	3	6	3	4	4	10/24/00				
236.		6	1	5	0	3	8	0		Lovqvist, et al.		_	
237.		6	1	6	2	8	1	6	12/19/00	Bohlin, et al.			
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EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Form PTO - 1449 (Modified)

FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE (Modified) PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. 40015630-0004	SERIAL NO. 09/481,207
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	APPLICANT J. Phillips	
(Use several sheets if necessary) (37 CFR 1.98 (b))	FILING DATE January 11, 2000	GROUP 1625

FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION

EXAMINER INITIAL	D	oci	JME	ENT	NU	JMB	ER		PUBLIC- ATION	COUNTRY OR		SUB	TRA LAT	
									DATE	PATENT OFFICE	CLASS	CLASS	YES	NO
238.		0	0	0	5	1	2	9	10/31/79	EPO A1 & B1			<u> </u>	
239.		0	2	4	4	3	8	ō	11/04/87	EPO A2 & B1		<u> </u>		
240.		0	2	4	7	9	8	3	12/02/87	EPO A2 & B1				
241.		0	3	0	8	5	1	5	03/29/89	EPO A1 & B1				
242.		0	3	1	5	9	6	4	05/17/89	EPO A1 & B1			<u> </u>	
243.		ō	3	9	4	4	7	1	10/31/90	EPO A1				
244.		0	0	4	0	6	3	9	12/02/81	EPO A1 & B1				
245.		0	4	1	4	8	4	7	03/06/91	EPO B1	·- · · · · · · · · · · · · · · · · · ·			
246.		0	4	3	6	6	2	0	07/17/91	EPO B1	-			
247.		0	4	5	2	6	9	7	10/23/91	EPO A1 & B1				
248.		0	4	6	5	2	5	4	01/08/92	EPO A1				
249.		0	4	9	6	4	3	7	07/29/92	EPO A2, B1 & A3		· · · · · · · · · · · · · · · · · · ·		_
250.		0	5	0	2	5	5	6	09/09/92	EPO A1 & B1				
251.		0	5	6	5	2	1	0	10/13/93	EPO A2, A3 & B1				
252.		0	5	6	7	2	0	1	10/27/93	EPO A2, A3 & B1				
253.		0	5	6	7	6	4	3	11/03/93	EPO A1				-
254.		0	5	8	7	6	5	9	03/23/94	EPO B1	-			
255.		0	6	5	2	7	5	1	05/17/95	EPO B1		<u> </u>		
256.		0	6	9	6	9	2	1	02/21/96	EPO B1				
257.	0	2	0	2	2	2	2	5	01/25/90	JP				
258.	0	3	0	3	4	9	6	7	02/14/91	JP				
259.	0	3	0	4	8	6	8	0	03/01/91	JP				
260.	0	3	0	5	2	8	8	7	03/07/91	JP				
261.	0	5	1	1	7	2	6	8	05/14/93	JP				
262.	0	5	1	9	4	2	2	4	08/03/93	JP				
263.	0	5	2	5	5	0	8	8	10/05/93	JP/English Trans. Attached				
264.	0	5	2	9	4	8	თ	1	11/09/93	JP/English Trans. Attached				
265.	0	6	0	9	2	8	5	3	04/05/94	JP				
266.	0	6	1	0	0	4	4	9	04/12/94	JP				
267.	0	7	0	3	3	6	5	9	02/03/95	JP				
268.	0	9	0	8	7	1	ᅱ	0	03/31/97	JP				
269.	1	0	0	1	7	4	7	0	01/20/98	JP				
270.	1	0	0	1	7	4	7	1	01/20/98	JP				
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272.	4	9	0	0	5	9	6	7	01/19/74	JP				
273.	4	9	0	1	3	1	7	2	02/05/74	JP				
274.	4	9	0	2	0	-	7	3	02/22/74	JP				
275.	4	9	0	2	0	1	7	4	02/22/74	JP				
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Form PTO - 1449 (Modified)

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT	APPLICANT J. Phillips	
(Use several sheets if necessary) (37 CFR 1.98 (b))	FILING DATE January 11, 2000	GROUP 1625

FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION

EXAMINER INITIAL	D	DOCUMENT NUMBER								COUNTRY OR		SUB	TRA	
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276.	4		0	9	3		3	7	09/05/74	JP				
277.	4	9	0	9	5	9	9	7	09/11/74	JP				
278.	5	0	0	5	2	0	6	5	05/09/75	JP				
279.	5	0	1	1	2	3	7	3	09/03/75	JP				
280.	5	0	1	4	2	5	6	5	11/17/75	JP				
281.	5	1	0	1	6	6	6	9	02/10/76	JP				
282.	5	1	0	1	7	2	6	8	08/27/77	JP				
283.	5	1	1	3	1	8	7	5	11/16/76	JP				
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285.	5	2	0	1	4	7	7	6	02/03/77	JP				
286.	5	2	0	9	7	9	7	8	08/17/77	JP				
287.	5	3	0	5	9	6	7	5	05/29/78	JP				
288.	5	5	0	1	9	2	1	1	02/09/80	JP				
289.	5	6	0	6	1	3	1	1	05/26/81	JP				
290.	5	9	0	9	5	9	9	7	06/02/84	JP				
291.	6	1	2	2	1	1	1	7	10/01/86	JP .				
292.	6	2	1	4	5	0	8	3	06/29/87	JP				
293.	6	2	2_	5	8	3	1	6	11/10/87	JP				
294.	6	2	2	5	8	3	2	0	11/10/87	JP	1			
295.	6	2	2	7	7	3	2	2	12/02/87	JP/English Trans. Attached	1			
296.	7	0	0	3	9	5	4	1	12/12/70	JP				
297.	7	0	0	3	9	5	4	3	12/12/70	JP				
298.	7	1	0	0	9	5	8	0	03/11/71	JP				
299.	7	1	0	0	9	5	8	1	03/11/71	JP				
300.	7	4	0	4	1	1	9	8	11/07/74	JP				
301.	8	0	0	1	9	2	1	1	05/24/80	JP				
302.	200	0	2	1	2	1	8	0	08/02/00	JP				
303.		8	9	0	0	5	6	6	01/26/89	WO A1				
304.		9	2	0	4	8	9	8	04/02/92	WO A1				
305.		9	2	0	8	7	1	6	05/29/92	WO A1				
306.		9	3	0	5	7	7	0	04/01/93	WO A1				
307.		9	4	0	2	1	4	1	02/03/94	WO A1				
308.		9	5	0	1	7	8	3	01/19/95	WO A1				
309.		9	5	0	7	9	1	3	03/23/95	WO A1				
310.		9	5	1	5	9	6	2	06/15/95	WO A1				
311.		9	5	2	3	5	9	4	09/08/95	WO A1				
312.		9	5	3	2	9	5	8	12/07/95	WO A1				
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT	APPLICANT J. Phillips	
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FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION

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									DATE	PATENT OFFICE	CLASS	CLASS	YES	NO
313.		9	5	3	2	9	5	9	12/07/95	WO A1				
314.		9	6	0	1	6	2	5	01/25/96	WO A1				
315.		9	6	1	6	9	5	9	06/06/96	WO A1				
316.		9	6	3	8	1	7	5	12/05/96	WO A1				
317.		9	7	0	9	9	6	4	03/20/97	WO A1				
318.		9	7	2	5	0	6	4	07/17/97	WO A1		_		
319.		9	.7.	2-	5	-0-	6	.6-	07/17/97	WO A1		-	–	
320.		9	8	1	6	2	2	8	04/23/98	WO A1				
321.		9	8	4	0	0	5	4	09/17/98	WO A1				
322.		9	9	4	5	0	0	4	09/10/99	WO A1				
323.		9	9	5	5	7	0	5	11/04/99	WO A1				
324.		9	9	5	5	7	0	6	11/04/99	WO A1				
325.		0	0	1	0	9	9	တ	03/02/00	WO A2 & A3				
326.		0	0	2	7	3	6	6	05/18/00	WO A1				
327.		0	0	2	8	9	7	5	05/25/00	WO A2 & A3				
328.		0	0	3	0	6	1	2	06/02/00	WO A1				
329.		0	0	3	5	4	4	8	06/22/00	WO A1			-	
330.		0	0	4	4	7	4	4	08/03/00	WO A1				
331.		0	0	4	5	8	1	7	08/10/00	WO A1				
332.		0	0	6	9	4	3	8	11/23/00	WO A1				
333.		0	0	7	8	2	9	3	12/28/00	WO A1				
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